

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
27 February 2003 (27.02.2003)

PCT

(10) International Publication Number
WO 03/016165 A1(51) International Patent Classification⁷: B65D 65/46, (74) Agents: LUMB, J., Trevor et al.; Pfizer Inc., 201 Tabor Road, Morris Plains, NJ 07950 (US).
81/32

(21) International Application Number: PCT/IB02/00230

(22) International Filing Date: 22 January 2002 (22.01.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/312,879 16 August 2001 (16.08.2001) US(71) Applicant (for all designated States except US):
WARNER-LAMBERT COMPANY [US/US]; 201 Tabor Road, Morris Plains, NJ 07950 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): SCOTT, Robert, Anthony [GB/BE]; Capsugel N.V., Rijksweg 11, B-2880 Bornem (BE). HUMPHRIES, Mark, Robson [GB/GB]; Manor Mead, High Street, Great Chesterford, Saffron Walden, Essex CB10 1PL (GB). SEENEY, Philip [GB/GB]; Gallow Brook House, Paxton Hill, Saint Neots, Cambridge PE19 6RA (GB). CREEKE, Sarah, Anne [GB/GB]; 78 Thornton Road, Girton, Cambridge CB3 0NN (GB).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

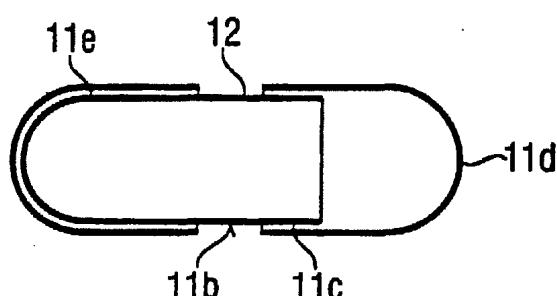
Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

A1

(54) Title: WATER SOLUBLE PACKAGING



WO 03/016165

(57) Abstract: The invention is concerned with controlled release packaging comprising packaging material which is at least partially or substantially completely dispersible or dissolvable in an effective amount of a water-containing substance and which is adapted to comprise, contain or enclose one or more substances wherein the packaging is adapted for release of comprised, contained or enclosed substances in response to a predetermined stimulus in predetermined manner to a desired locus with substantially simultaneous or subsequent partial or complete dispersal or dissolving thereof.

WATER SOLUBLE PACKAGING

The present invention relates to improved packaging which is at least partially or substantially completely dissolvable in water for controlled release of substances, methods for controlled release using the packaging, methods for the production 5 thereof, the use for release of a wide range of substances and novel products comprising the packaging.

Water soluble packaging is known in the literature for dispensing substances, with partial or complete dissolution thereof leaving little or no residue. Such packaging materials are used in isolation as self supporting packaging or are used in 10 combination with non soluble dispensers. These packaging materials release contained substances such as, hazardous substances, fungicides etc., concentrates such as detergents and the like on dissolution in water.

The advantages of such packaging is readily apparent, by way of reducing splash or spillage risk with hazardous substances during dilution, containing hazardous 15 powder substances prior to dissolution and preventing the risk of inhalation, avoiding the need for safe disposal of used packaging material for hazardous substances and the like, providing pre-metered dosing in prescribed quantities as individual packages, convenient handling, minimising wastage of substance dregs, package disposal and the like.

20 In some uses it is acceptable to have an amount of residue remaining for example as a surface film, although this is undesirable in certain uses.

With larger quantities of substance to be released, there is a risk of fracture or failure of the packaging. In EP-A-763479 (Rhone Poulenc Agric Limited) is disclosed such packaging in which the liquid substance to be released contains an 25 additive to increase its viscosity. Such solutions to the problem are however not entirely satisfactory and therefore there is a need for water soluble packaging which is sufficiently resilient to reliably contain a substance until the desired point of dispensing.

Encapsulation technology using water soluble capsule material is known in the pharmaceutical industry for delivery of pharmaceuticals, vitamins, supplements and the like by oral ingestion using gelatin, cellulose and derivatives as encapsulating materials. Gelatin, cellulose and derivatives and the like are substantially completely dissolvable in water and are approved capsule material for food and drug use. These capsules are intended for dissolving over a range of periods under different conditions within the body.

Dissolvable gelatin sachets are known in the literature for containing and preserving powdered flavouring, colouring and other substantially dried food components as part of pre-packed food such as dehydrated noodles in a pot into which hot water is added in order to prepare the food for consumption. Failure or fracture of such sachets can lead to deterioration of contents.

There is a continual need for improved packaging materials and configurations to potentially extend the useful applications and uses of a number of water soluble packaging materials.

It is an object of the present invention to provide packaging which is at least partially or substantially completely dispersible or dissolvable in water-containing substances for controlled release of a wide range of diverse solid and fluid substances in a wide range of diverse forms, whereby the packaging is versatile and easily manipulated to the intended substance or use in desired manner.

We have now surprisingly found that packaging comprising materials which are at least partially or substantially completely dissolvable in water-containing materials may be adapted according to the present invention to provide novel combinations of formulation and configuration suited for release of contained or enclosed substances in manner to meet the objective as hereinbefore defined.

In its broadest aspect there is provided according to the present invention controlled release packaging comprising packaging material which is at least partially or substantially completely dispersible or dissolvable in an effective

amount of a water-containing substance and which is adapted to comprise, contain or enclose one or more substances wherein the packaging is adapted for release of comprised, contained or enclosed substances in response to a predetermined stimulus in predetermined manner to a desired locus with substantially 5 simultaneous or subsequent partial or complete dispersal or dissolving thereof.

The substance to be released may be in the form of solid or liquid and is preferably selected from powders, granules, crystals, microcapsules, monoliths, suspensions, dispersions, concentrates, gels, thixotropes, non-aqueous solutions and the like and mixtures thereof. Solid substances may be in a desired grade or range of grades.

10 For certain applications it is desired to provide substance in fine and coarse form for prolonged effect. It is an advantage of the present invention that individual doses of substance contain the desired range of solid grade and are not subject to the disadvantages of „settling“ which result from transport and storage of volumes of the substance, or with combinations of substances having different particle 15 grades.

Substance to be released may be integral with the water-dispersible or soluble packaging material which may be in the form of a solid or hollow mass, a hollow container or enclosure of a separate container and/or contained or enclosed within the hollow mass, container or enclosure.

20 The packaging is characterised by novel selection of features or combinations of features of packaging conformation and/or configuration, packaging material formulation and the like, in manner to provide novel selection of properties or combinations of properties. More specifically the packaging is characterised by novel selection of features or combinations relating to handling and storage, for example in manner to resist influences leading to premature release by means of package formulation conformation or configuration including sealing and reinforcing thereof; nature of comprised, contained or enclosed substances which may be viscous or non viscous fluid, non compactable flowable powder and other forms of substance which are not easily manipulated or controlled; nature and/or 25

timing of release for example for releasing one or a combination of substances in simultaneous or subsequent fashion, or for releasing substances in manner to contact other substances in the desired locus for improved substance performance or quality for the intended use; nature of predetermined release stimulus and the 5 like, for example being the water-containing substance itself, a physical or chemical stimulus in the desired locus or a combination thereof. Features and properties may derive from the water-soluble or dispersible packaging material and/or from additional materials or substances formulated, conformed or configured with the water-dispersible or soluble packaging material, or from the 10 conformation or configuration of the packaging, and are selected according to the intended use.

The packaging may consist substantially entirely of water-dispersible or soluble packaging material or combinations thereof as hereinbefore defined or may 15 comprise additional materials as hereinbefore defined which are at least partially dispersible or dissolvable or otherwise. Preferably the packaging is substantially completely dissolvable as hereinbefore defined.

Reference herein to a water-containing substance is to any solid, semi-solid, liquid or gaseous (vapour) fluid which comprises water in effective dispersing or dissolving amount. Water may be chemically or physically releasably bound or 20 may be freely available and may be gathered or accumulated from the substance or readily and instantly taken up by the material. Preferably a water-containing substance as hereinbefore defined comprises liquid- or vapour-form water, or aqueous solutions or vapour mixtures thereof with liquids or vapours such as alcohols and the like, or comprises solids or semi-solids having bound or available 25 water. Water may be accumulated by the water-dispersible or soluble packaging material which at least partially disperses or dissolves to release the comprised, contained or enclosed substance into the accumulated water and the dispersed or dissolved packaging material may be retained in the locus or dispersed therefrom in the course of the intended use or otherwise.

Reference herein to a predetermined stimulus is to any stimulus causing release of contained or enclosed substance. The stimulus may comprise chemical or physical stimulus for dissolving or dispersing, transforming by precipitation or morphology change, fracturing, rupturing or otherwise rendering permeable the packaging or a 5 part thereof to release contained or enclosed substance.

The stimulus may be the same as or different to the water-containing substance which serves to disperse or dissolve. Packaging materials may be dispersible or soluble in hot or cold water-containing substance and/or may release substance by dissolution or by other physical or chemical means such as exposure to heat, acid 10 or alkali, solvents and solvent mixtures, oxidising conditions, radiant energy including UV, microwave and the like or biological degradants.

Reference herein to a locus is to any place, area or the like into or at which it is desired to release the substance. The locus may be the same as or may be different to but connecting with a locus at which the substance is to have a desired effect.

- 15 Preferably the packaging comprises a primary and secondary component in terms of conformation, configuration or formulation adapted to dissolve and release the substance to the desired locus and to control stimulus or external influences to which the release element is subjected in manner to provide release with pre-determined timing and in pre-determined manner.
- 20 The packaging may comprise any suitable material which is capable of being formed into packaging, and which is dispersible or dissolvable in water-containing substance to leave only a part thereof as residue or to leave substantially no residue. Preferably the water-dispersible or soluble packaging material comprises a natural or synthetic polymer or mixtures thereof selected from:
- 25 Polyvinyl alcohol (PVA), polyethyleneoxide, chemically modified cellulose or cellulose ethers and other cellulose derivatives, modified starches, polyvinylpyrrolidone, polyacrylamide or gelatine or derivative thereof. Chemically modified cellulose and cellulose ethers include alkyl- and/or hydroxyalkyl

substituted cellulose or cellulose ether with 1 to 4 carbon atoms in the alkyl chain preferably methyl cellulose (ether), hydroxyethyl cellulose, hydroxyethylmethyl cellulose, hydroxyethylethyl cellulose, hydroxypropyl cellulose (having the chemical name cellulose hydroxypropylether), hydroxypropylmethyl cellulose 5 (HPMC, having the chemical name cellulose hydroxypropylmethylether), hydroxybutylmethyl cellulose and the like. Modified starches include destructureised starch, cross-linked granular starches, chemically modified starches including alkyl substituted starches, amino starches and oxidised starches, dextrin and maltodextrins.

10 Water-dispersible or soluble packaging material is suitably selected or adapted according to independent mechanical properties or combinations thereof („soft“ or „hard“ and/or self-supporting or non self-supporting, resilient to premature fracture or otherwise and the like) and/or independent chemical properties and combinations thereof (slow or rapid, complete or partial dissolving, responsive to 15 desired release stimulus and the like), requirements of non-toxicity (for environment, human or animal health or food-related uses and the like). For example different formulations and combinations of water dispersible or soluble packaging material(s) may be provided having desired combination of properties by varying or selecting the moisture content, pH, moisture retention, swelling 20 properties, gel strength, gel point, viscosity, concentration, reacting substituent groups (cross-linking) and sensitivity to a number of external stimuli such as temperature, pH, solvents and solvent mixtures, oxidising conditions, radiant energy such as UV or microwave, biological degradation by moulds and bacteria and the like. Formulations and formulation techniques are known for example as 25 disclosed in Hard Capsules, ed. Ridgeway, WO 98/27151 (Warner Lambert) the contents of which are incorporated herein by reference.

Preferred packaging materials include gelatin, starch or cellulose or derivatives and mixtures thereof which are substantially completely soluble in water. Natural or synthetic gelatin and HPMC are found to have particularly useful properties.

The packaging of the present invention may be of any desired conformation and configuration suited to contain or enclose a solid or fluid substance as hereinbefore defined. Preferably the packaging comprises packaging material in the form of solid or hollow masses, hollow containers or closures such as capsules, bags, 5 wallets or sachets, spherical, pyramidal, elongate, annular or conical bags and the like or closures such as membranes, partitions, caps, lids and the like. The conformation or configuration may be selected according to control requirements, storage requirements (stackable or able to be stored in space efficient manner i.e. cubes), use (adapted to be configured to locate in or in association with a support 10 means of an environment), dispensable (adapted to be releaseably attached to a dispensing line, hook, rack or the like for convenient access), and the like.

The packaging as hereinbefore defined may provide a primary structure or region of packaging material for strengthening, reinforcing, retaining package integrity during release or other such purpose, such as a skeleton, frame work, fibres, mesh, 15 ribbing, webbing, seal or the like integral with or at least partially (co)-continuous with a secondary structure of substantially continuous packaging material in desired configuration.

Alternatively or additionally the packaging may comprise a primary containing or enclosing shell or layer in the form of a sheath, tablet or the like containing or 20 enclosing a secondary containing or enclosing layer of packaging material.

Alternatively or additionally the packaging may comprise primary packaging material having secondary points of weakness in the form of packaging material formulated for rapid or easy dissolving or fracture, or of flaws or water entraining features such as moulding or embossing in the form of non-penetrating 25 perforations, tear-off strip lines and the like.

Primary and secondary structures and layers and point of weakness packaging material as hereinbefore defined may be comprised of the same or different packaging materials and combinations thereof as hereinbefore defined, having

same or different properties such as thickness and the like. Different packaging materials include at least one packaging material being a water-dispersible or soluble packaging material which may be the same as or different to at least one being a packaging material adapted for release as hereinbefore defined.

5 Alternatively or additionally the packaging may comprise means for locating or positioning within the locus into which a contained substance is to be released in manner to secure it at the optimum position for storing, or for timing or activating the release stimulus for example for the operation of dissolving water in the locus on the release element, or to maintain the packaging in desired position in manner
10 to withstand influences such as impact force during handling and storage and the like.

Such locating means may comprise packaging material as hereinbefore defined adapted to engage a suitable support, for example may comprise an elongate substantially resilient or flexible portion adapted to be tied or hooked onto or located around a suitable projection or received within a recess of an effective support in the environment in which the packaging is contained, or may comprise resiliently deformable projections extending in opposing directions from the containing or enclosing packaging material as hereinbefore defined and adapted to be deformed to locate between opposing retaining means, surfaces and the like of an effective support means and be retained by resilience.
20

Alternatively or additionally the packaging comprises a specific configuration, conformation or formulation adapted to absorb or dispel external influences to which the packaging may be subjected and which may lead to premature release of contained or enclosed substance. For example the packaging may confer a protective shape on contained or enclosed fluid substance to minimise turbulence in storage and handling and/or may comprise packaging material of thickness, strength, resilience, flexibility and the like adapted to withstand external influences.
25

Packaging as hereinbefore defined may be adapted to be self-supporting.

Alternatively or additionally packaging as hereinbefore defined comprises means to aid rapid release of contained or enclosed substance. In this case the packaging comprises means to enhance the response thereof to release stimulus, by means of formulation or of additional components incorporated in or contained within the

5 packaging. Preferably response enhancing means are adapted to cause release by expanding on contact with water-containing substances, for example comprise swelling or expanding agents (maize starch), effervescent agents (sodium bicarbonate and citric acid), disintegrants (ExplotabTM available from Penwest Pharmaceuticals or PrimojelTM available from Avebe), dispersing agents (sodium

10 starch glycolate, sodium alginate, carboxymethylcellulose sodium salt and the like) or contained gases, such as air at a positive overpressure and the like, stimulus sensitising agents, for example adapted to cause release on change of pH (change in degree of acid or alkali conditions or transition therebetween), change in temperature, subjecting to microwave, UV, solvents and solvent mixtures and the

15 like. Response enhancing means may be integral with packaging packaging material or contained in open or closed porosity therein to provide increased surface area and weak points as hereinbefore defined for release for example by dissolving action on contact with water, and to provide expansion of contained air on change of temperature, contact of effervescent agents with water, microwaves,

20 UV, solvents and solvent mixtures and the like.

In a further aspect of the invention there is provided a method for the production of packaging as hereinbefore defined comprising forming packaging material as hereinbefore defined, and introducing one or more substances to be released as hereinbefore defined in manner to be comprised, contained or enclosed therein.

25 The manufacture may be carried out in a single operation or in desired sequence, depending on the intended use, substance to be released and form of packaging. The production method may be adapted to confer any features of formulation conformation, configuration and the like as hereinbefore defined.

The packaging may be formed by any known means for forming packaging materials as hereinbefore defined. Suitable means include any means for forming thermoplastic materials including residue free sealing one or more sheets, deforming one or more sheets by action of heat, solvents such as water, vacuum, 5 pressure and the like, extruding, shaping from solution or molten, for example by dipping or spraying onto a former, casting, embossing etc.

Substance(s) may be comprised, contained or enclosed within the packaging material by any known mechanical or chemical means including coforming the material and substance for example by fusing, blending or mixing into a molten 10 packaging material or a solution thereof, or sealing the packaging material about the substance(s) for example by softening the packaging material with water or a sensitising agent and self bonding to unsoftened or similarly softened packaging material, bonding or welding with solvent, glue and the like with or without application of heat or pressure. Preferably sealing is by techniques as disclosed in 15 patent publications in the name of Capsugel, specifically by contacting edges of packaging material with a melting point depression sealing fluid such as organic solvents for example alkyl substituted C₁₋₅ alcohols, water, a polymer solution or emulsion, a solution of a proteolytic enzyme producing a protein solution and the like, and applying thermal energy or the like to cause fusion, for example as 20 disclosed in relation to sealing of capsules in EP 0 152 517, EP 0 180 543, EP 0 116 744, and EP 0 116 743, the contents of which are incorporated herein by reference.

Points of weakness as hereinbefore defined may be provided in the packaging material by known means, for example embossing or moulding in the shape of the 25 packaging by necking and the like, by laser exposure or by pre-determined orientation or ordering of molecules within the chemical structure of the packaging.

Packaging as hereinbefore defined may be adapted to contain any desired quantity or volume of solid or liquid substance. Suitably the form and configuration of package is selected in part with reference to the desired volume and the nature of

the substance to be contained or enclosed. Preferably the packaging is adapted to contain volumes of up to 10 litres of substance, for example in the range 0.1 ml up to 10 litres. Sub ranges for envisaged applications are preferably in the range of 0.1-5 ml, 5-50 ml, 50-500 ml, 500 ml – 5 litres and 5-10 litres. The packaging may

5 be adapted to have a volume substantially equal to that of the substance to be contained or greater than, e.g. up to three times the volume of the substance to be contained. The packaging volume may be selected according to ease of filling with substances. Suitably packaging is adapted to contain or enclose a single measure dose of one or more substances to be released.

10 Packaging may be adapted for clustering or may include a clustering element. Packaged substance may be clustered or aggregated by means of self adhesion, clustering attachment and the like in the case that a single measure exceeds the volume of substance which it is possible to contain or enclose or in the event that dosing is according to preference, or in the case that a selection of substances are to

15 be released simultaneously or in controlled sequence.

Packaging may comprise multiple compartments to segregate substances prior to release, or to provide sequential release.

Packaging as hereinbefore defined may include an identification element, for example may be printed, moulded directly or indirectly for example by forming

20 flexible packaging material tightly about a contained substance having moulded protrusions, or embossed, laser-marked or the like to indicate the nature or origin of the contents, the mode of use, or to incorporate features of design. Printing is preferably by means of inks, dyes and the like which are completely dissolvable in water and which are adapted to be printed from non aqueous solutions or from

25 aqueous solutions.

Packaging as hereinbefore defined may be adapted to release substances substantially instantaneously on contact with water-containing substances as hereinbefore defined or in a controlled period of the order of minutes for immediate

use, quarter or a half hour period for example when it is desired to prime the packaging and evacuate the environment for release, hours or days for example where it is desired to prime the packaging for release during a period at which it is inconvenient or impossible to access the locus, or on response to a stimulus, for 5 example where it is desired to release substances in the event of natural or artificial water release, such as to coincide with rain or intentional or unintentional water release that is part of any chemical, mechanical, construction, manufacturing or the like process.

10 The packaging may be provided with additional agents adapted to enhance barrier properties for example to confer or enhance impermeability to oxygen and the like.

Packaging may be provided as one piece or as a plurality of pieces to be assembled at the time of filling with substrate, for example using conventional or modified capsule technology.

15 Packaging may be of any desired thickness, for example in the range 0.01 – 10 mm. It is a particular advantage of the present invention that minimal thickness for example in the range 0.01 – 1.0 mm may be attained with resilience to unintentional rupture, and that maximum thickness for example in the range 2 – 10 mm may be attained with desired precision of timing of release, by means of the selection of properties and features of formulations of packaging material, 20 conformations such as solid mass of packaging material or configurations such as structures and points of weakness of packaging of the invention as hereinbefore defined.

25 It should be appreciated that packaging material as hereinbefore defined may be adapted to maintain the integrity of the packaging prior to release of substances and to dissolve or disperse simultaneously with release or to subsequently disperse or dissolve over a prolonged period whilst still contained within the desired locus in contact with water-containing substance, during the period that the substance which has been released is effective, or thereafter.

Packaging may be provided within an additional film or container if it is important to keep the surface free from contamination.

Packaging or substance to be contained may comprise an additional indicating element, for example a component which indicates when dissolution is complete or 5 when the substance has achieved its desired effect. A colorant within the substance is detectable in the aqueous locus once dissolution is sufficiently advanced to release substance. The colorant may be associated with the substance whereby the colour disappears once substance is consumed in use.

In a further aspect of the invention there is provided a method for the controlled 10 release of a substance as hereinbefore defined from water-dispersible or soluble packaging material as hereinbefore defined comprising locating the packaging in a locus for intended release and subjecting to a release stimulus, for example contacting with water-containing substance as hereinbefore defined in effective dispersing or dissolving amount, for an effective period to activate release as 15 hereinbefore defined and release the substance into the locus, wherein the packaging is substantially simultaneously or subsequently at least partially or substantially completely dissolved in the water-containing substance. The packaging may comprise any features of conformation, configuration or formulation as hereinbefore defined.

20 The method provides advantages of reducing splash or spillage risk with hazardous substances during dilution, containing hazardous powder substances prior to dissolution and preventing the risk of inhalation, avoiding the need for safe disposal of used packaging material for hazardous substances and the like, providing pre-metered dosing in prescribed quantities as individual packages, 25 convenient handling, minimising wastage of substance dregs, package disposal and the like.

The method for controlled release as hereinbefore defined may be for any desired use for which it is intended to release a substance into an environment with any of the advantages as hereinbefore mentioned.

5 The packaging may be located directly in the desired locus or may be transported to the desired locus by suitable means, maintained out of contact with water-containing substance.

10 The packaging of the invention may be adapted to sink or float in water when added to a reservoir of water at the desired locus, or to initially sink or float and subsequently after a pre-determined interval float or sink prior to or at the time of release of contents, for example as indicating means or to maximise or minimise water content prior to release and the like.

15 The method may be for release of agrochemical substances including pest or plant growth control agents, plant disease control agents, soil improvement agents and the like. For example pest growth control agents include insecticides, miticides, rodenticides, molluscicides, slugicides, vermicides (nematocides, antihelminthics), soil fumigants, pest repellents and attractants such as pheromones etc., and biological control agents such as microorganisms, predators and natural products; plant growth control agents include herbicides, defoliants, desiccants, fruit drop and set controllers, rooting compounds, sprouting inhibitors, growth stimulants and 20 retardants, moss and lichen controllers and plant genetic controllers or agents; plant disease control agents include fungicides, viricides, timber preservatives and bactericides; and soil improvements agents include fertilisers, trace metal additives, bacterial action control stimulants and soil consolidation agents.

25 The method may be for farming, greenhouse, horticultural, forestry and like applications on industrial or domestic scale by means of spraying, dusting, drilling and like techniques.

The advantages of the method include advantages as hereinabove defined and may include further advantages of safe handling including reduced risk of

contamination or carry over and no skin contact with active substance, convenience and ease of use, without measuring, decanting or re-sealing of part used sachets, dispensing with the need to dispose of contaminated packaging, precise dose control, avoiding user exposure to dust particles, providing solubility in cold water, 5 providing greater flexibility in selection of dose amounts and with commercially available granules, reducing the risk of product deterioration once opened, optimising particle size for dissolution and use of minimal packaging. Further advantages include non clogging with spray nozzles and the like, no need for using a stirrer, no residue remaining, leak proof robust packaging and low cost per dose 10 per unit area.

The method is also suited for release of environmental treatment agents such as water purification agents, disinfectants, waste treatment agents and the like, including control agents for water borne viruses, bacterium, organisms and insects which carry disease, natural and industrial contaminants including water borne 15 plant growth control agents, soil run off dispersant agents, cooling and recycled water neutralising agents and the like. Advantages are as given above for agricultural use and include advantages of employing approved substances for use in purifying drinking water, and providing high quality of water which is not contaminated by particles or undissolved solid packaging material or residue, and 20 speed of purifying action. Substances may be released into water or the desired locus in desired concentration suited for the desired effect, for example in lower amounts to render safe for consumption or in higher amounts to create a solution for application to an object or locus to be purified, disinfected or treated.

The method may be used for handling safe-to-the-point-of-use substances, for 25 example hazardous substances including caustics, chemical reagents, drain clearing substances and the like which may be used in diluted form, which are relatively safe although unpleasant in powdered, non-aqueous or concentrate form but which become hazardous in solution. In this case a unit dose packaging may be provided which is safe to handle and which ensures correct dilution, and safety to the point

of use. This may provide advantages as above defined in addition to further advantages such as eliminating the need to transport bulk substances in hazardous diluted form, by providing a means for the safe dilution by the end user.

The method may be used for releasing detergents and their components in the form of solids or liquids such as concentrates, including domestic and industrial detergents for cleaning premises, objects and clothing and for personal hygiene using any known detergents or cleaning agents. The advantages include those given above, and additionally include aesthetic advantages by which the packaging leaves no deposit on the hands and is more pleasant to handle than powders or tablets, is structurally of high integrity preventing break up or spillage risk of the substance, has a reduced risk of product deterioration once a primary pack is opened and associated extended shelf life, has potentially more efficient and effective delivery of key ingredients, is easier to manufacture, formulate and use and gives a reduced risk of concentrate damage to clothes, skin and other articles, and renders optional the use of bags or devices from which to release the substance, additionally having the advantages of minimising the required amount of softening agents, bleaches, brighteners, dispersants, effervescent and other solubilising agents including phosphates. These components typically otherwise deteriorate with time or may be poorly distributed throughout the detergent, enabling dosing of multi-function substances in a single dose or sequential dosing in a single package for example having one substance embedded or enclosed within a further substance within the packaging, minimising volume to weight ratio and the like.

The method may also be used to release food components including flavours and fragrances in the form of dried or powdered solids, liquids and volatiles, texturising agents, colorants, moisture absorbers such as rice, corn flour, salt and the packaging material itself, oils and fats, dried dairy products and other food products which deteriorate in the presence of oxygen, seasoning and herbs and the like. The method for releasing food substances has advantages as indicated above and additional advantages in terms of precise dose control providing sizes linked to

standard culinary measures for example, separation of ingredients without using packs that need to be opened by the user, for example in instant food packs, environmentally friendly avoiding non edible secondary packaging, microwaveable, no risk of contamination with secondary packaging fragments, 5 clean and easy handling, edible packaging, no susceptible residue in hot water, sealing from air, preserving freshness and shelf life, taste and smell masking until required, for example to avoid contaminating other food components or the like, preservation of vitamins, colour, purity of flavour and the like. In a particular advantage packaging may be used to minimise deterioration of substances due to 10 contact in storage by separating and simultaneously may provide for improved dispersibility and contact on release by positioning food components in manner for optimum contact on release.

In a further aspect of the invention there is provided novel products comprising packaging as hereinbefore defined. Suitably novel products include products 15 adapted for the specific methods as hereinbefore defined with the associated advantages. The products may be provided for filling with substance(s) for release or may be provided containing the substance(s). The products may comprise packaging having features of conformation, configuration and formulation as hereinbefore defined.

20 The invention is now illustrated in non limiting manner with reference to the following figures wherein

Figures 1a – 1i are sectional and view diagrams of packaging according to the invention comprising primary packaging material having secondary points of weakness;

25 Figures 2a and 2b are sectional and view diagrams of packaging according to the invention comprising primary and secondary structures, and conformation options thereof;

Figures 3a and 3b with enlarged views are sectional and view diagrams of packaging according to the invention including locating means;

Figures 4a – 4c are views of configurations of packaging according to the invention with manufacturing method;

5 Figures 5a and 5b are views of clustering elements and clustered packaging according to the invention.

In Figure 1 is shown in each case packaging in the form of conformations and configurations typically obtained by dipping from molten or solutions of packaging materials. In Figures 1a to 1g are shown capsules comprising water-dispersible or 10 soluble multiple layers and/or multiple sections of material in the form of peripheral shells (11) and linking portions (12, 13).

Figure 1a shows a capsule having central monolayer of rapid dissolve packaging material and peripheral bilayers of rapid-slow and slow-rapid dissolve packaging material respectively, adapted to provide a weak link or point of weakness as 15 hereinbefore defined. In Figure 1b is shown a capsule having central and peripheral monolayers of rapid dissolve and slow dissolve packaging materials respectively and peripheral bilayer of rapid-slow dissolve packaging material, as an alternative to the configuration of Figure 1a. Variations of these configurations are envisaged and may be determined according to the desired ease of manufacture and desired 20 release characteristics.

The capsule of Figure 1a may be manufactured for example by forming peripheral shells (11a inner, 11d outer) by dipping a former to a first depth into respective solutions of or molten slow and rapid dissolve packaging material respectively, then forming shell (11a outer) by dipping to a greater depth into a solution of or 25 molten rapid dissolve packaging material, simultaneously creating portion (11b) and finally filling and overlap capping the portion (11b) with shell (11d outer), simultaneously creating seal (11c).

The capsule of Figure 1b may be manufactured for example by forming shells (11e inner, 11d) as for 11a inner and 11d outer above, then forming shell (11e outer) by dipping the inner to a lesser depth in slow dissolve packaging material, and filling and overlap capping shell (11d) simultaneously forming seal (11c).

- 5 Figures 1c and 1d show capsules peripheral shells which are shrunk fit about (shaped or moulded) substance and have therebetween secondary points of weakness in the form of an easy dissolving region (12) having an area adapted to peel back, for example on swelling in the form of an unsealed abutment of the two peripheral shells (11d).
- 10 Figures 1e and 1f show capsules comprising an easy dissolving packaging material band (13) bridging a gap between shells (11d). Solid or liquid ingredients are enclosed within the capsule (11d, 11d) and released via the easy dissolving region (13) on rapid dissolution in water.

Figures 1g shows a capsule comprising a rapid dissolve monolayer peripheral shell 15 (11f) enclosing substance and inner secondary peripheral shell (11d), abutting or overlap sealed to the capsules remote peripheral shell (11d). The capsule may be suited to enclose two same or different substances with staged release, with rapid release of one substance via the rapid dissolve shell (11f) and subsequent release of the second substance by slow dissolve of capsule (11d, 11d).

- 20 In Figures 1h and 1i are shown packaging in the form of a primary dipped bag or wallet (14) which is filled and sealed, with a separate cap portion (15) or by self-sealing by crimping (16) as illustrated. Crimping may optionally provide a release feature in the form of a primary structure as a point of strength portion to prevent premature release or as a secondary point of weakness portion which is for example adapted for rapid dissolving in water to release contents of the bag with subsequent dissolution of the bag or wallet.

In Figures 2a and 2b are shown a sachet in the form of secondary structure packaging material (21) located around a primary structure mesh bag of slow

dissolving reinforcing packaging material (22) which may be fused or otherwise with the packaging material (21). Packaging material (21) is sealed at the edges.

This packaging is suited for delivery of graded substances whereby rapid dissolving of packaging material (21) releases fine particles from within the 5 primary structure mesh bag (22), large particles being released later on slow dissolving of mesh bag (22). The sachet may comprise packaging material (21) as flexible or rigid packaging material or a combination thereof which may be flat or formed, for example by vacuum. This configuration may also be employed in other embodiments according to the invention as hereinbefore defined using any 10 packaging material as desired.

In Figure 3a is shown water-soluble capsule (31) in the form of a first capsule portion, retained by means of a resiliently deformable capsule shell (32) on a support means (33) in locus (34). By locating the water soluble capsule (31) on support means (33) external influences of locus (34) leading to premature release 15 are minimised. On contact with water the shell (31) dissolves releasing contents, with subsequent dissolution of the locating shell (32).

In Figure 3b is shown a capsule which may be made of water soluble packaging material adapted to be located by means of resiliently deformable wings, thereby locating a capsule in position and potentially damaging external influences within 20 the locus.

In Figures 4a – 4c are shown configurations of packaging constructed of packaging material (41) with soluble seal or crimp (42). Packaging may be constructed by means including flow wrapping or extruding to form a seamed or seamless tube with seamed sectioning along the length, as shown in Figures 4b(i) and 4b(ii). In 25 Figures 5a and 5b are shown clustering elements comprising water soluble packaging material (52) according to the invention and clustered water-soluble packaging in the form of capsules (51). On contact with water the clustered capsules dissolve rapidly to release their contents with subsequent dissolution of

the clustering element which serves to aid withstanding external influences leading to premature release prior to contact with water.

CLAIMS

1. Controlled release packaging comprising packaging material which is at least partially or substantially completely dispersible or dissolvable in an effective amount of a water-containing substance and which is adapted to comprise, contain or enclose one or more substances wherein the packaging is adapted for release of comprised, contained or enclosed substances in response to a predetermined stimulus in predetermined manner to a desired locus with substantially simultaneous or subsequent partial or complete dispersal or dissolving thereof.
5
2. Packaging according to Claim 1 wherein the substance to be released is in the form of solid or liquid and is preferably selected from powders, granules, crystals, microcapsules, monoliths, suspensions, dispersions, concentrates, gels, thixotropes, non-aqueous solutions and the like and mixtures thereof, in a desired grade or range of grades.
10
3. Packaging according to Claim 1 or 2 characterised by features or combinations of features of packaging conformation and/or configuration and/or packaging material formulation, in manner to provide selection of properties or combinations of properties, wherein features and properties derive from the water-soluble or dispersible packaging material and/or from additional materials or substances formulated, conformed or configured with the water-dispersible or soluble packaging material, or from the conformation or configuration of the packaging and are selected according to the intended use.
15
4. Packaging according to any of Claims 1 to 3 which is substantially completely dissolvable.
20
5. Packaging according to any of Claims 1 to 4 which is dispersible or dissolvable in water-containing substance comprising any solid, semi-solid, liquid or gaseous (vapour) fluid which comprises water in effective dispersing or dissolving amount, which may be chemically or physically releasably bound or may be freely available
25

and may be gathered or accumulated from the substance or readily and instantly taken up by the packaging material.

6. Packaging according to any of Claims 1 to 5 adapted for release in response to a predetermined stimulus comprising any chemical or physical stimulus for dissolving or dispersing, transforming by precipitation or morphology change, fracturing, rupturing or otherwise rendering permeable the packaging or a part thereof to release contained or enclosed substance.
7. Packaging according to any of Claims 1 to 6 wherein the stimulus is the same as or different to the water-containing substance which serves to disperse or dissolve, wherein materials are dispersible or soluble in hot or cold water-containing substance and/or may release substance by dissolution or by other physical or chemical means such as exposure to heat, acid or alkali, solvents and solvent mixtures, oxidising conditions, radiant energy including UV, microwave and the like or biological degradants.
8. Packaging according to any of Claims 1 to 7 for release of substance into a locus comprising any place, area or the like into or at which it is desired to release the substance, which may be the same as or may be different to but connecting with a locus at which the substance is to have a desired effect.
9. Packaging according to any of Claims 1 to 8 comprising a primary and secondary component in terms of conformation, configuration or formulation adapted to dissolve and release the substance to the desired locus and to control stimulus or external influences to which the release element is subjected in manner to provide release with pre-determined timing and in pre-determined manner.
10. Packaging according to any of Claims 1 to 9 wherein water-dispersible or soluble packaging material comprises a natural or synthetic polymer or mixtures thereof selected from polyvinyl alcohol (PVA), polyethyleneoxide, chemically modified cellulose or cellulose ethers and other cellulose derivatives, modified starches, polyvinylpyrrolidone, polyacrylamide or gelatine or derivatives thereof.

11. Packaging according to any of Claims 1 to 10 in the form of solid or hollow masses, hollow containers or closures such as capsules or sachets or spherical, pyramidal, elongate, annular or conical bags and the like or closures such as membranes, partitions, caps, lids and the like.
- 5 12. Packaging according to any of Claims 1 to 11 comprising a primary structure or regions of packaging material for strengthening, reinforcing, retaining package integrity during release or other such purpose, such as a skeleton, frame work, fibres, mesh, ribbing, webbing, seal or the like integral with or at least partially (co-)continuous with a secondary structure of substantially continuous packaging material.
- 10 13. Packaging according to any of Claims 1 to 12 comprising a primary containing or enclosing shell or layer in the form of a sheath or tablet containing or enclosing a secondary containing or enclosing layer of packaging material.
14. Packaging according to any of Claims 1 to 13 comprising primary packaging material having secondary points of weakness in the form of packaging material formulated for rapid or slow dissolving or fracture, or of flaws or water entraining features such as moulding or embossing in the form of non-penetrating perforations, tear-off strip lines.
- 15 15. Packaging according to any of Claims 1 to 14 comprising means for locating or positioning within the locus into which a contained substance is to be released in manner to secure it at the optimum position for storing, or for timing or activating the release stimulus for example for the operation of dissolving water in the locus on the release element, or to maintain the packaging in desired position in manner to withstand influences such as impact force during handling and storage.
- 20 16. Packaging according to any of Claims 1 to 15 wherein locating means comprise an elongate substantially resilient or flexible portion adapted to be tied or hooked onto or located around a suitable projection or received within a recess of an effective support in the environment in which the packaging is contained, or

may comprise resiliently deformable projections extending in opposing directions from the packaging material as hereinbefore defined and adapted to be deformed to locate between opposing retaining means, surfaces and the like of an effective support means and be retained by resilience.

- 5 17. Packaging according to any of Claims 1 to 16 comprising a conformation, configuration or formulation adapted to absorb or dispel external influences to which the packaging may be subjected and which may lead to premature release of contained or enclosed substance.
- 10 18. Packaging according to any of Claims 1 to 17 comprising means to enhance the response thereof to release stimulus, by means of formulation or of additional components incorporated in or contained within the packaging, selected from means adapted to cause release by expanding on contact with water-containing substances, for example comprising swelling or expanding agents, effervescent agents, disintegrants, dispersing agents, or contained gases, such as air at a positive 15 overpressure and the like, stimulus sensitising agents, for example adapted to cause release on change of pH, change in temperature, subjecting to microwave, UV, solvents and solvent mixtures and the like.
- 20 19. Method for the production of packaging as hereinbefore defined in any of Claims 1 to 18 comprising forming packaging material and introducing one or more substances to be released in manner to be comprised, contained or enclosed therein.
- 25 20. Method according to Claim 19 wherein forming packaging materials is by residue free sealing one or more sheets, deforming one or more sheets by action of heat, solvents such as water, vacuum, pressure and the like, extruding, shaping from solution or molten, for example by dipping or spraying onto a former, casting, embossing etc.
21. Method according to any of Claims 19 and 20 comprising containing or enclosing the substance to be released by sealing by mechanical or chemical means

including softening the packaging material with water or a sensitising agent and self bonding to unsoftened or similarly softened packaging material, bonding or welding with solvent, glue, contacting edges of packaging material with a melting point depression sealing fluid such as organic solvent, water, a polymer solution or 5 emulsion, a solution of a proteolytic enzyme producing a protein solution and the like, and applying thermal energy or the like to cause fusion.

22. Method according to any of Claims 19 to 21 wherein packaging includes an identification element, for example may be printed, moulded, embossed or laser marked to indicate the nature or origin of the contents, the mode of use, or to 10 incorporate features of design.

23. Method according to any of Claims 19 to 22 wherein packaging or substance to be contained comprises an additional indicating element, for example a component which indicates when dissolution is complete or when the substance has achieved its desired effect.

15 24. Method for the controlled release of a substance as hereinbefore defined employing water-dispersable or soluble packaging as hereinbefore defined comprising locating the packaging in a locus for intended release and subjecting to a release stimulus, for example contacting with water- containing substance in effective dispersing or dissolving amount, for an effective period to activate release 20 as hereinbefore defined and release the substance into the locus, wherein the packaging is simultaneously or subsequently substantially completely dissolved in the water containing substance.

25. Method according to Claim 24 for release of agrochemical substances including pest or plant growth control agents, plant disease control agents, soil improvement agents and the like for farming, greenhouse, horticultural, forestry and like applications on industrial or domestic scale by means of spraying, dusting, drilling and like techniques.

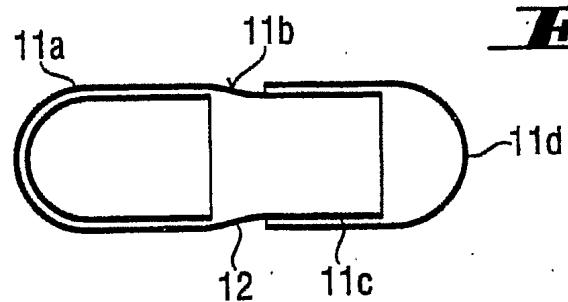
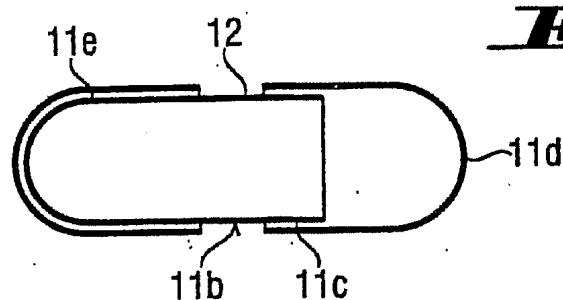
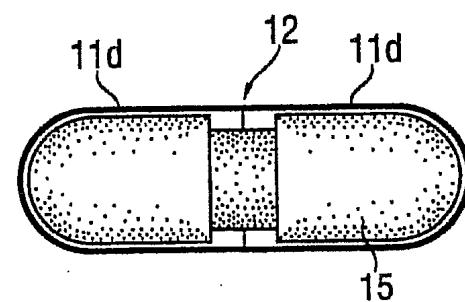
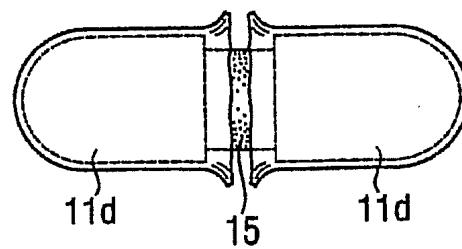
26. Method according to Claim 24 for release of environmental treatment agents such as water purification agents, disinfectants, waste treatment agents and the like, including control agents for water borne viruses, bacterium, organisms and insects which carry disease, natural and industrial contaminants including water borne 5 plant growth control agents, soil run off dispersant agents, cooling and recycled water neutralising agents and the like.

27. Method according to Claim 24 for handling and release of safe-to-the-point-of-use substances, for example hazardous substances including caustics, chemical reagents, drain clearing substances and the like which may be used in diluted form, 10 which are relatively safe although unpleasant in powdered, non-aqueous or concentrate form but which become hazardous in solution.

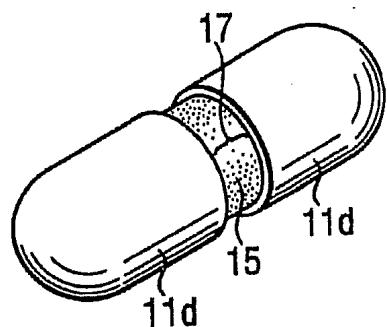
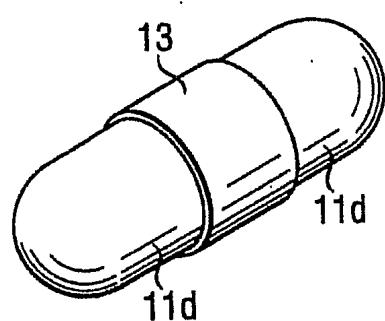
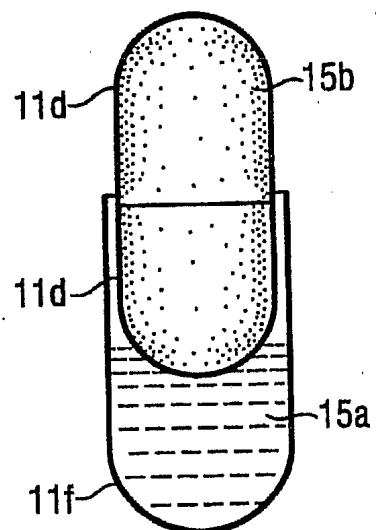
28. Method according to Claim 24 for releasing detergents or other cleaning agents in the form of solids or liquids such as concentrates, including domestic and industrial detergents for cleaning premises, objects and clothing and for personal 15 hygiene using any known detergents or cleaning agents.

29. Method according to Claim 24 for release of food components including flavours and fragrances in the form of dried or powdered solids, liquids and volatiles, texturising agents, colorants, moisture absorbers such as rice, corn flour, salt and the packaging material itself, oils and fats, dried dairy products and other 20 food products which deteriorate in the presence of oxygen, seasoning and herbs and the like.

1 / 8

***Fig. 1a******Fig. 1b******Fig. 1c******Fig. 1d***

2 / 8

Fig. 1e**Fig. 1f****Fig. 1g**

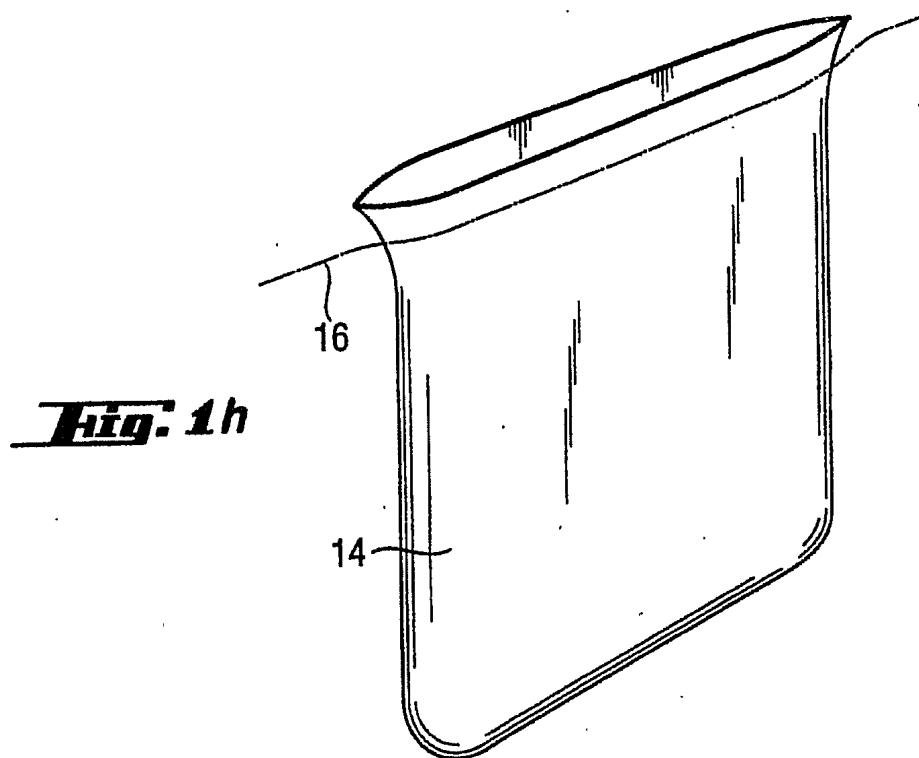


Fig. 1h

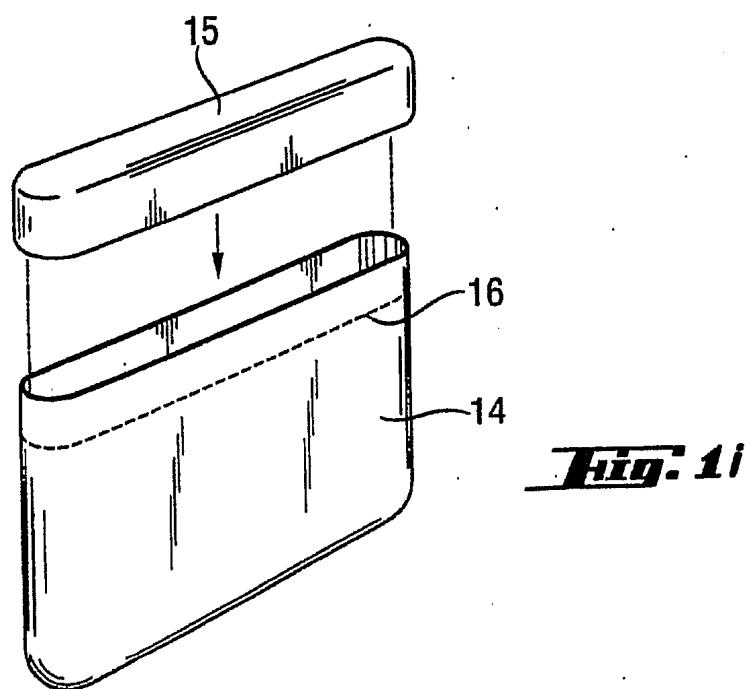
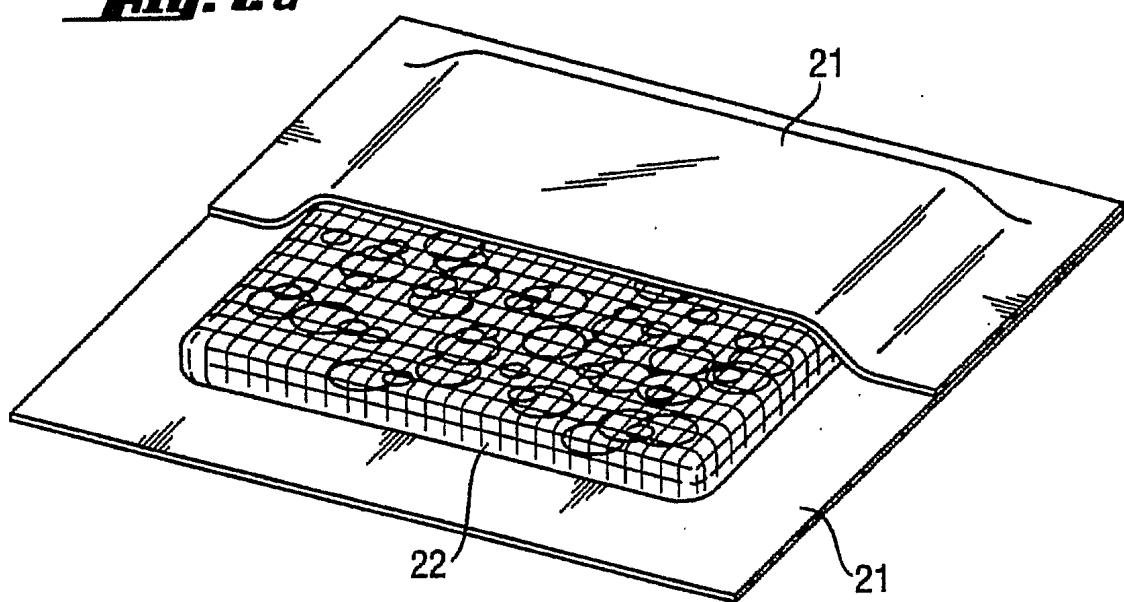
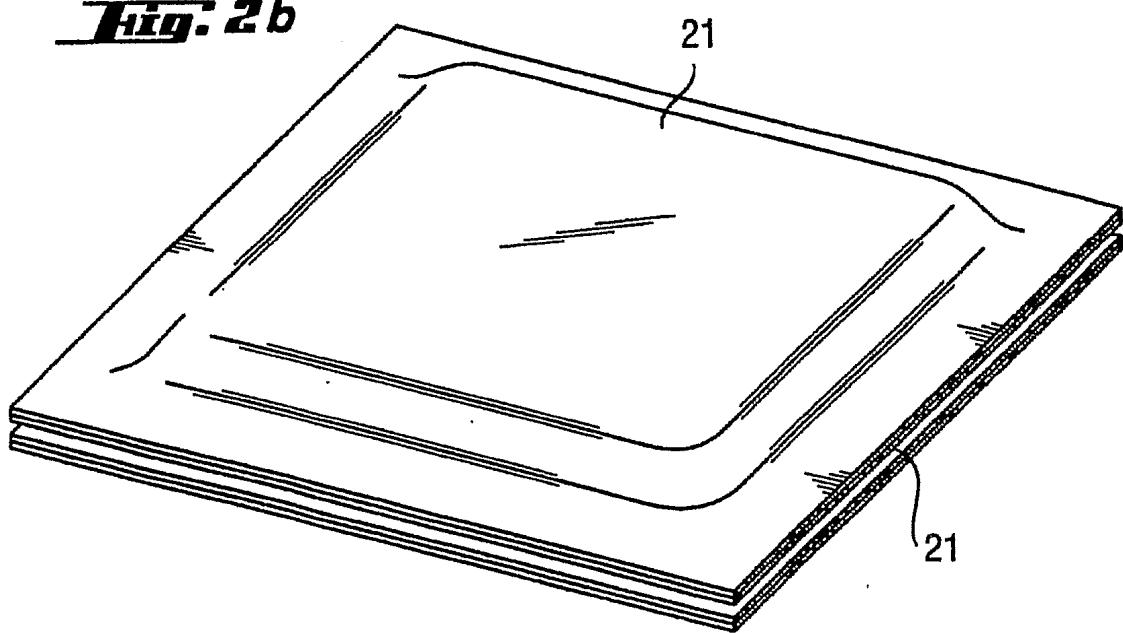


Fig. 1i

4 / 8

Fig. 2a***Fig. 2b***

5 / 8

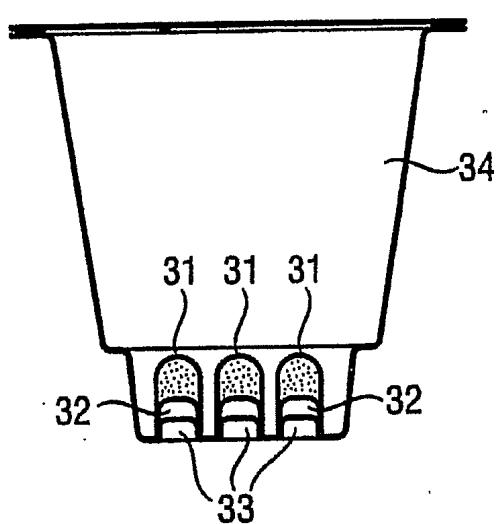


Fig. 3

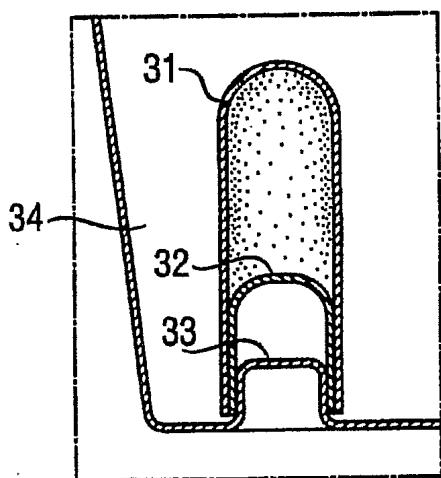


Fig. 3a

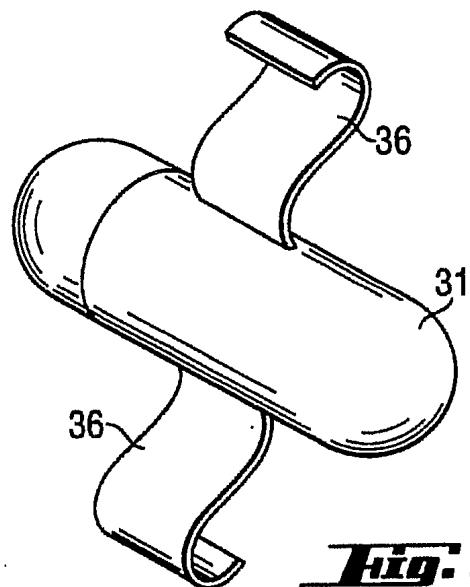


Fig. 3b

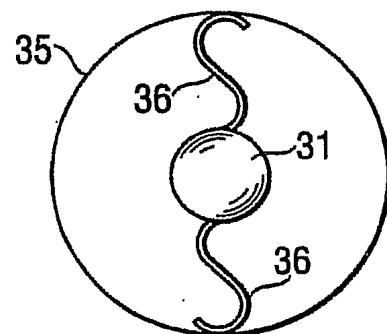
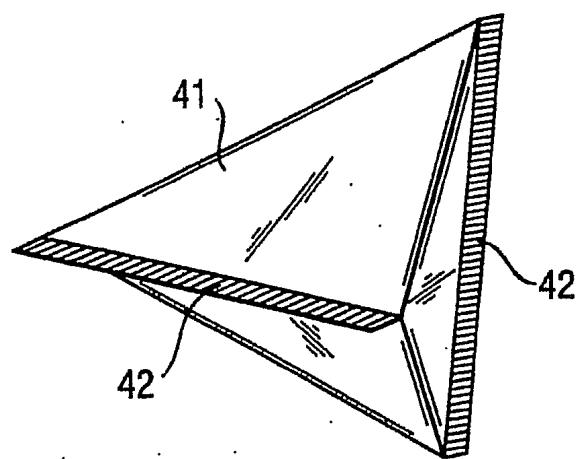
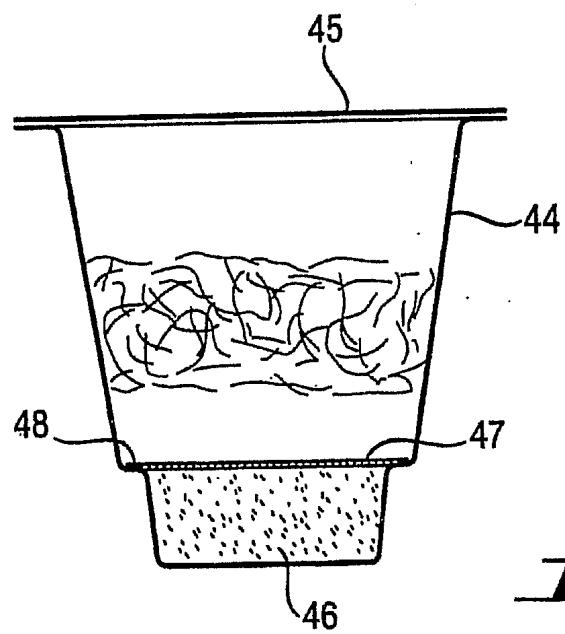
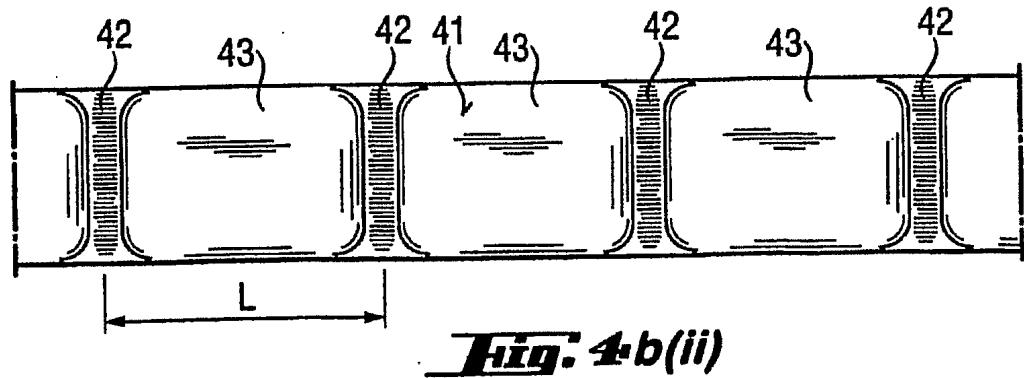
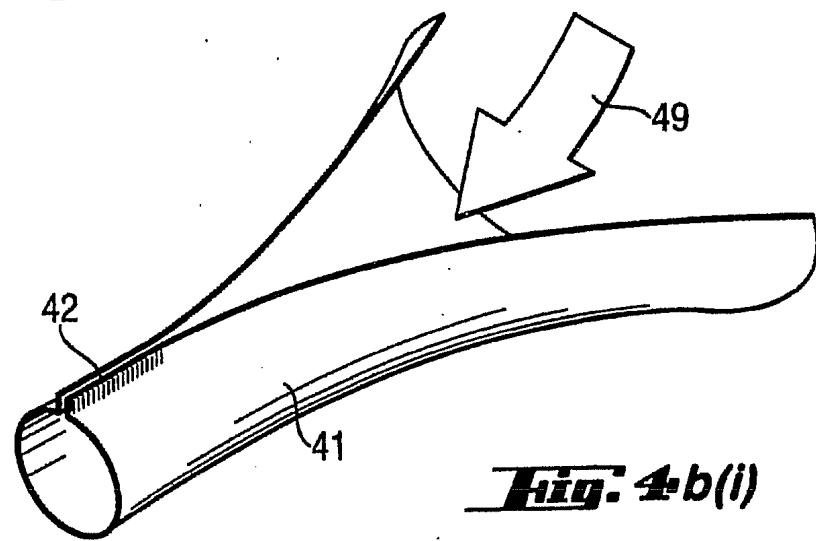
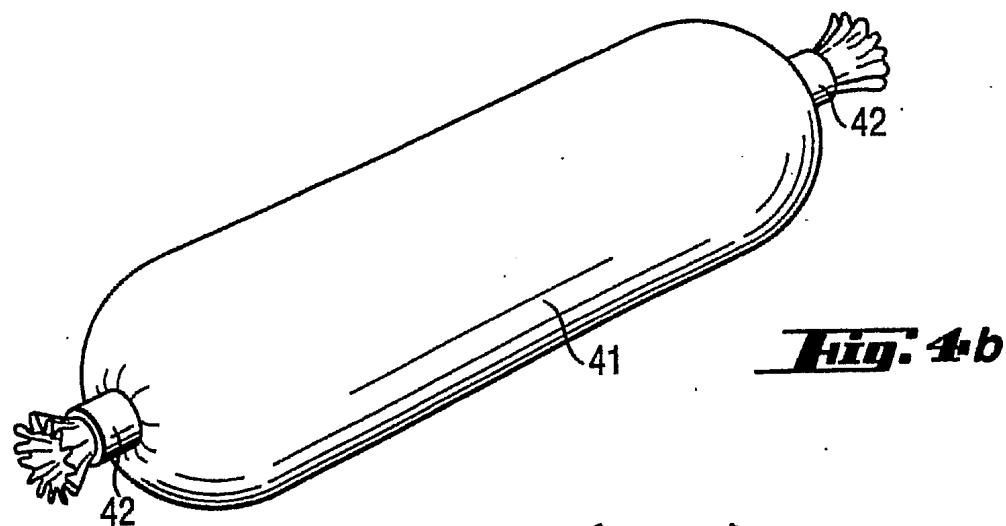


Fig. 3c

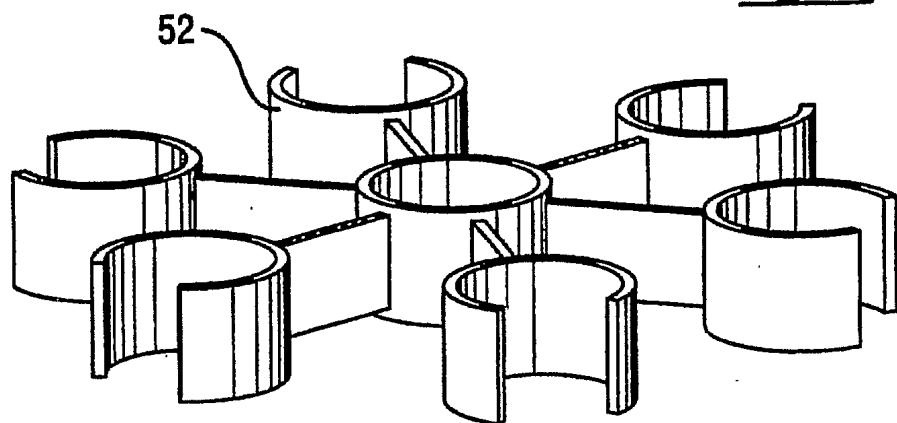
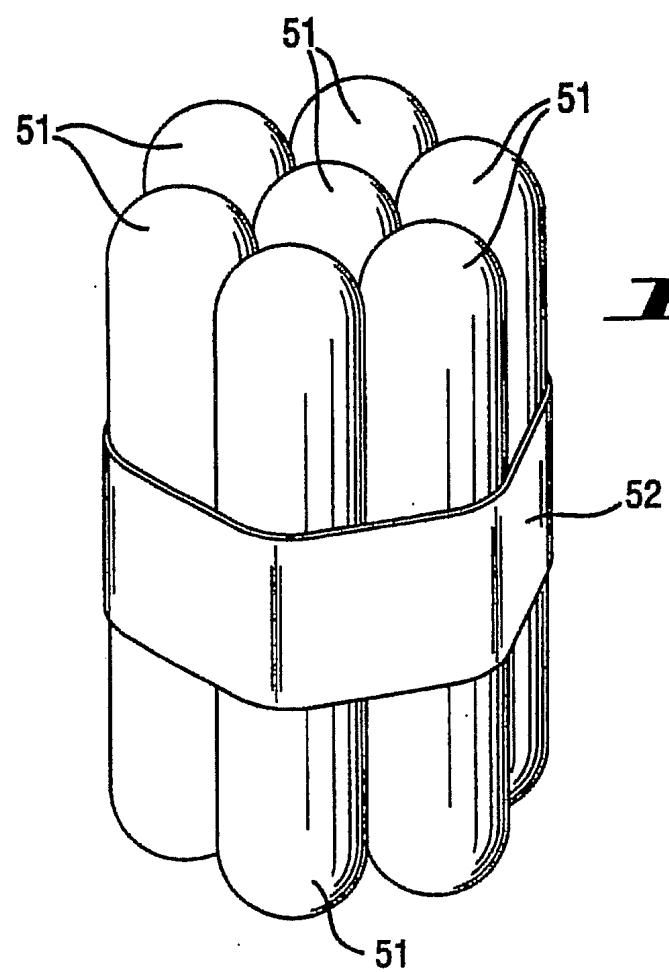
6 / 8

***Fig. 4a******Fig. 4c***

7 / 8



8 / 8

Fig. 5a***Fig. 5b***

INTERNATIONAL SEARCH REPORT

Int'l. Application No

PCT/IB 02/00230

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 B65D65/46 B65D81/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 IPC 7 B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 195 37 671 A (BOSCH GMBH ROBERT) 17 April 1997 (1997-04-17)	1-11,13, 18,24,28
Y	the whole document	12, 14-17, 25-27,29
Y	US 3 762 454 A (WILKINS R) 2 October 1973 (1973-10-02)	12
X	the whole document	1-3
Y	DE 79 10 284 U (SEIBT & KAPP GMBH MASCHF) 12 July 1979 (1979-07-12)	14
X	the whole document	1
Y	US 3 915 296 A (SPENCER RICHARD HUGH H) 28 October 1975 (1975-10-28)	15-17,29
X	the whole document	1-3,18, 24

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents:

- °A° document defining the general state of the art which is not considered to be of particular relevance
- °E° earlier document but published on or after the international filing date
- °L° document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- °O° document referring to an oral disclosure, use, exhibition or other means
- °P° document published prior to the international filing date but later than the priority date claimed

- °T° later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- °X° document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- °Y° document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- °&° document member of the same patent family

Date of the actual completion of the international search

18 July 2002

Date of mailing of the International search report

25/07/2002

Name and mailing address of the ISA
 European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Pernice, C

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 93 08095 A (RHONE POULENC AGROCHIMIE) 29 April 1993 (1993-04-29)	19-21
Y	the whole document	22, 23, 25-27
Y	--- "ETIKETTENMATERIAL AUS WASSERLOESLICHES PAPIER UND KLEBER" VERPACKUNGS RUNDSCHEIN, VERLAG P.KEPPLER K.G. HEUSENSTAMM, DE, vol. 42, no. 8, 1 August 1991 (1991-08-01), page 958 XP000290191 ISSN: 0341-7131 the whole document	22
Y	US 3 580 390 A (SHULL JOHN D JR) 25 May 1971 (1971-05-25)	23
X	the whole document	1-8, 10, 18, 24
X	--- EP 0 941 939 A (KEMTEC INTERNATIONAL INC) 15 September 1999 (1999-09-15)	1-11, 18, 24
	the whole document	-----

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
DE 19537671	A 17-04-1997	DE	19537671 A1	17-04-1997
US 3762454	A 02-10-1973	NONE		
DE 7910284	U 12-07-1979	DE	7910284 U1	12-07-1979
US 3915296	A 28-10-1975	NONE		
WO 9308095	A 29-04-1993	AP 343 A AT 158775 T AU 2880692 A BR 9206780 A CA 2121799 A1 CN 1071637 A CZ 9400972 A3 DE 69222537 D1 DE 69222537 T2 WO 9308095 A1 EP 0608340 A1 FI 941884 A HU 67862 A2 IL 103507 A JP 7500301 T MX 9206111 A1 NZ 244818 A PL 169961 B1 PT 101005 A TR 27430 A US 5224601 A ZA 9208139 A	03-06-1994 15-10-1997 21-05-1993 31-10-1995 29-04-1993 05-05-1993 17-08-1994 06-11-1997 26-02-1998 29-04-1993 03-08-1994 22-04-1994 14-03-1995 14-05-1996 12-01-1995 01-08-1993 27-09-1994 30-09-1996 29-04-1994 15-04-1995 06-07-1993 29-07-1993	
US 3580390	A 25-05-1971	NONE		
EP 0941939	A 15-09-1999	EP	0941939 A1	15-09-1999